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(71) Applicants and

(72) Inventors: STARKE, Gregory, Richard [ZA/ZA]; 17 Moss Street, Fernwood Estate, Newlands 7700 (ZA). LEHMANN, Markus [ZA/ZA]; 35 Connaught Road, Kenilworth 7700 (ZA). CONWAY, Damian, John [ZA/ZA]; 3 Disa avenue, Observatory 7925 (ZA).

(74) Agent: BACON, Brian; Brian Bacon & Associates, 2nd floor, Mariendahl House, Fedsure on Main, Main Road, 7700 Newlands (ZA).

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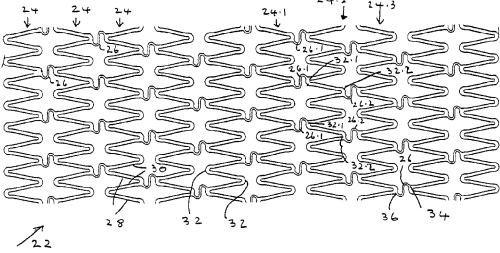
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STENTS



(57) Abstract: A stent (22) of cylindrical form is disclosed which comprises a plurality of rings (24) extending around the stent's longitudinal axis. The rings (24) are spaced apart along the axis and are joined to one another by longitudinals (26) each of which spans between one ring and an adjacent ring. Each ring (24) is of zig-zag form and comprises bars (28) all of which are parallel to one another and bars (30) all of which are parallel to one another and at an angle to the bars (28). The bars (28, 30) alternate and are joined to one another by way of hairpin bends (32). the longitudinals (26) join the hairpin bends (32) of one ring to the hairpin bends (32) of the adjacent ring. Each of the rings has, between each adjacent pair of longitudinals (considered in the circumferential direction) at least two, or any multiple of two, hairpin bends (32) which are not joined to hairpin bends (32) of the adjacent ring.



STENTS

FIELD OF THE INVENTION

THIS INVENTION relates to stents.

BACKGROUND TO THE INVENTION

A stent is used medically in any one of a multiplicity of vessels of the human body to maintain its patency.

Applicant is aware of European patent specifications EP 0 669 114 B1, EP 0 821 920 B1 and EP 0 821 921 A1 and US specifications 5733303, 5195984, 5102417, 4733665, 6179867, 5514154, 6068656, 6190403, 5913895 and 5643312 which disclose stents of various types.

The object of the present invention is to provide a stent with improved radial expansion capabilities and minimal longitudinal contraction during radial expansion.

BRIEF DESCRIPTION OF THE INVENTION

According to one aspect of the present invention there is provided a stent of cylindrical form which comprises a plurality of rings extending around the stent's

longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, characterized in that each ring is of zig-zag form and comprises a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the hairpin bends of one ring to the hairpin bends of the adjacent ring, each of these rings having between each adjacent pair of longitudinals, considered in the circumferential direction, at least two, or any multiple of two, hairpin bends which are not joined to hairpin bends of the adjacent ring.

Each bar preferably has end portions contiguous with the hairpin bends that join it to adjacent bars and a centre portion which joins said end portions to one another, the centre portion being of non-linear configuration.

Each ring can be a mirror image of the ring, or rings, adjacent thereto about radial planes passing through the midpoints of the longitudinals.

In a specific form said one ring and said adjacent ring each comprise three first bars, three second bars and five hairpin bends between each of said adjacent pairs of longitudinals thereby providing the two non-joined hairpin bends on the facing

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sides of said rings and three hairpin bends on the sides of the rings which face away from another, the centre ones of these hairpin bends being joined by longitudinals to further rings.

According to another aspect of the present invention there is provided a stent of cylindrical form which comprises a plurality of rings extending around the stent's longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, each ring being of zig-zag form and comprising a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the hairpin bends of one ring to the hairpin bends of the adjacent ring, each of these rings having between each adjacent pair of longitudinals, considered in the circumferential direction, at least two, or any multiple of two, hairpin bends which are not joined to hairpin bends of the adjacent ring, each longitudinal connecting a first ring to a second ring being midway between, considered in the circumferential direction, two further longitudinals which connect the first ring to a further ring and midway between two additional longitudinals which connect the second ring to another ring, the further longitudinals being spaced the same circumferential distance from one another as the two additional longitudinals are spaced from one another and which is the same distance as the spacing between the

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longitudinals connecting the first and second rings.

According to a further aspect of the present invention there is provided a stent of cylindrical form which comprises a plurality of rings extending around the stent's longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, each ring being of zig-zag form and comprising a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the bends of one ring to the bends of the adjacent ring, each longitudinal being of sinusoidal or generally sinusoidal form, there being a first junction where one end of the longitudinal is joined to one ring and a second junction where the other end of the longitudinal is joined to an adjacent ring, said first junction being displaced circumferentially around the stent with respect to the second junction, each ring being a mirror image of the adjacent ring whereby each hairpin bend of said one ring is axially aligned with one of the hairpin bends of said adjacent ring.

Each group of three rings can comprise a centre ring, a first adjacent ring on one side of the centre ring and a second adjacent ring on the other side of the centre ring, alternate hairpin bends on one side of the centre ring being joined by

longitudinals to the first adjacent ring and alternate hairpin bends on the other side of the centre ring being joined by longitudinals to the second adjacent ring.

In a configuration which reduces stress concentrations at the hair pin bends, each bar of the stent can be narrower considered in the circumferential direction, than the width of the hairpin bends considered in the axial direction.

To improve radio opacity each bar of the stent can have a centre section and end sections on each side of the centre section, the end sections being narrower, considered in the circumferential direction, than the centre section.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:-

- Figure 1 illustrates a stent in layflat form;
- Figure 2 illustrates another stent in layflat form;
- Figure 3 illustrates a detail of a stent;
- Figure 4 illustrates a further stent detail;
- Figure 5 illustrates a number of bars and hairpin bends of a stent; and
- Figure 6 illustrates a further form of stent.

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DETAILED DESCRIPTION OF THE DRAWINGS

Referring firstly to Figure 1 the stent 10 illustrated is of cylindrical form and comprises a plurality of rings 12 which extend around the stent's longitudinal axis. For ease of illustration the stent has been shown in the form it adopts if split longitudinally and flattened.

The rings 12 are spaced apart along the longitudinal axis of the stent and are joined to one another by longitudinals 14 which span between one ring 12 and an adjacent ring 12.

Each ring 12 is of zig-zag form and comprises a plurality of first bars 16 all of which are parallel to one another and a plurality of second bars 18 all of which are parallel to one another and at an angle to the bars 16. Bars 16 alternate with bars 18.

The bars are joined to one another by way of hairpin bends 20.

Each longitudinal 14 joins a hairpin bend 20 of one ring 12 to a hairpin bend 20 of the adjacent ring. This arrangement enables longitudinals of sufficient length to be obtained without having to increase the spacing between adjacent rings.

As will be seen from Figure 1, not all the hairpin bends are joined to one another. More specifically, between each pair of longitudinals and the hairpin bends

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joined by them, considered in the circumferential direction, each ring 12 has two hairpin bends 20 which are not joined to the hairpin bends of adjacent rings. To distinguish between them, the hairpin bends of one pair of joined hairpin bends have been designated 20.1 and a non-joined pair 20.2.

Each longitudinal is of S-configuration, one end of each longitudinal being spaced from the other end both in the axial direction of the stent and also in the circumferential direction of the stent. This arrangement enables longitudinals of sufficient length to be obtained without having to increase the spacing between adjacent rings.

Each bar 16, 18 is non-linear in configuration. More specifically each bar 16 has end portions 16.1, 16.2 which are approximately straight and in alignment with one another and a centre portion 18.3 which is of non-linear curved configuration and joins the end portions 16.1, 16.2 to one another.

A consideration of Figure 1 reveals that each ring 12 is a mirror image of the adjacent ring. To illustrate this the rings 12.1 and 12.2 are mirror images of one another about the line AA.

Turning now to Figure 2, the illustrated stent 22 is again shown in longitudinally split flat form. The stent comprises a plurality of rings 24 which extend

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around the stent's longitudinal axis and are spaced apart along the axis. The rings 24 are joined to one another by longitudinals 26 which span between one ring 24 and an adjacent ring 24.

Each ring 24 is of zig-zag form and comprises a plurality of bars 28 all of which are parallel to one another and a plurality of bars 30 which are also parallel to one another. The bars 28 are at an angle to the bars 30, bars 30 alternating with bars 28 and each bar 30 being joined at each thereof to two adjacent bars 28 by way of hairpin bends 32.

The longitudinals 26 join the bends 32 of one ring 24 to the bends 32 of the adjacent ring. Each longitudinal 26 is of sinusoidal form. There is a junction at 34 where one end of the longitudinal 26 is joined to one hairpin bend 32 and another junction at 36 where the other end of the longitudinal is joined to an adjacent ring. Each first junction 34 at one end of a longitudinal 26 is displaced circumferentially around the stent with respect to the second junction 36 between that longitudinal and the adjacent ring. This again permits longitudinals 26 to be obtained which are of a length sufficient to counter stent shortening on radial expansion.

The configuration of the stent is such that the rings can be considered to be in groups of three. Three rings forming a group are designated 24.1, 24.2 and 24.3 in Figure 2. The centre ring 24.2 of the group is joined to the rings on both sides

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thereof. More specifically, alternate hairpin bends, designated 32.1, on one side of the centre ring 24.2 are joined by longitudinals designated 26.1 to the ring 24.1 on one side thereof and alternate hairpin bends 32.2 on the other side of the centre ring 24.2 are joined by longitudinals designated 26.2 to the ring 24.3.

When the cylindrical stent is expanded, the hairpin bends 20 open out to enable the diameter of the stent to be increased. Inevitably the opening out of the bends tends simultaneously to narrow each ring in the axial direction. Straightening of the longitudinals accommodates this narrowing of the rings without foreshortening the stent.

To minimise the strains imposed on the stent during expansion, it can have the configuration shown in Figure 3. In this form the width W1 of the hairpin bends is greater than the width W2 of the bars. This concentrates the greatest areas of stress away from the hairpin bends and reduces the prospects of stress at the bends fracturing the bends.

The stents described above are of an eight cell design. A stent of six cell design has less metal content than a stent of eight cell design. In order to improve the radio opacity of a six cell stent, it preferably has the configuration shown in Figure 4. In this form the width W3 of the centre section of each bar is greater than the width W4 of each end section of each bar and also greater than the width of the hairpin bend.

The stent shown in Figure 5 comprises bars 38 and hairpin bends 40. To provide for local delivery of drugs to the site of implantation, the bars have slots 42 cut through them or grooves or recesses 44 cut into them. Where grooves or recesses are provide, these can be on the radially inner faces of the bars, or the radially outer faces or both. Areas of high plastic deformation must be avoided when choosing the positions for the slot and/or grooves. The slots and/or grooves provide reservoirs in which slow release drugs can be located within a polymer substrate or other binder. More or larger slots can be provided where there is a greater need for drug elution. The ends of the stent are places where higher drug concentrations can be required. The drugs are released into the tissue or bloodstream over a period of time.

The stent shown in Figure 6 has rings designated 46, 48 and 50. The bars are designated 52, 54 and the hairpin bends 56.

The bars 52, 54 of the ring 46 are longer than the bars of the ring 48 which in turn are longer than the bars of the ring 50. If the bars of the rings towards the ends of the stent are shorter than the bars of the rings towards the middle of the stent, this provides for greater stiffness towards the ends of the stent. This resists flaring o the ends of the stent as it is expanded. It will be understood that any arrangement of bar lengths can be chosen to provide ring-like zones of greater strength and ring-like zones of lesser strength in any desired pattern.

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It is also possible to provide rings with different stiffnesses by varying the widths of the hairpin bends, considered in the axial direction. Thus hairpin bends of greater axial width can be provided at the ends of the stent to resist flaring of the ends during expansion. The widths of the hairpin bends in the axial direction will always be greater than the widths of the bars in the circumferential direction. Thus in Figure 3 W2/W1 will always be greater than 1.

The bars can include through slots and/or recesses for receiving drugs which are to be released into the recipient of the stent.

To provide rings of differing stiffness the widths of the hairpin bends, measured in the axial direction, can vary from one ring to another. A similar variation in stiffness can be provided by means of bars which in one ring are of a different length to the bars in another ring.

CLAIMS:

- 1. A stent of cylindrical form which comprises a plurality of rings extending around the stent's longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, each ring being of zig-zag form and comprising a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the hairpin bends of one ring to the hairpin bends of the adjacent ring, each of these rings having between each adjacent pair of longitudinals, considered in the circumferential direction, at least two, or any multiple of two, hairpin bends which are not joined to hairpin bends of the adjacent ring.
- 2. A stent as claimed in claim 1, wherein each bar has end portions contiguous with the hairpin bends that join it to adjacent bars and a centre portion which joins said end portions to one another, the centre portion being of non-linear configuration.
- 3. A stent as claimed in claim 1 or 2, wherein each ring is a mirror image of the ring, or rings, adjacent thereto about radial planes passing through the midpoints of

the longitudinals.

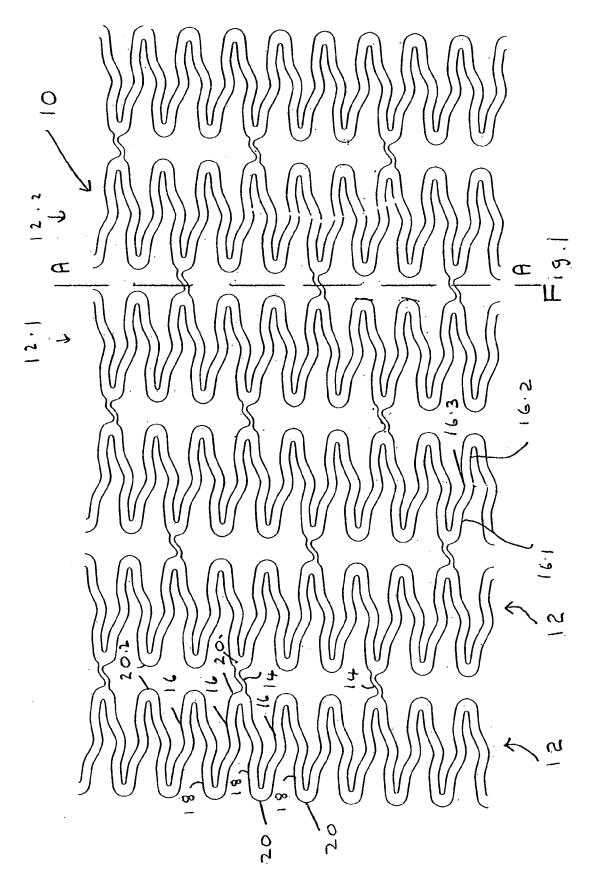
- A stent as claimed in claim 1 or 2, wherein said one ring and said adjacent ring each comprise three first bars, three second bars and five hairpin bends between each of said adjacent pairs of longitudinals thereby providing the two non-joined hairpin bends on the facing sides of said rings and three hairpin bends on the sides of the rings which face away from another, the centre ones of these hairpin bends being joined by longitudinals to further rings.
- A stent of cylindrical form which comprises a plurality of rings extending around the stent's longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, each ring being of zig-zag form and comprising a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the hairpin bends of one ring to the hairpin bends of the adjacent ring, each of these rings having between each adjacent pair of longitudinals, considered in the circumferential direction, at least two, or any multiple of two, hairpin bends which are not joined to hairpin bends of the adjacent ring, each longitudinal connecting a first ring to a second ring being midway between, considered in the circumferential direction, two further longitudinals

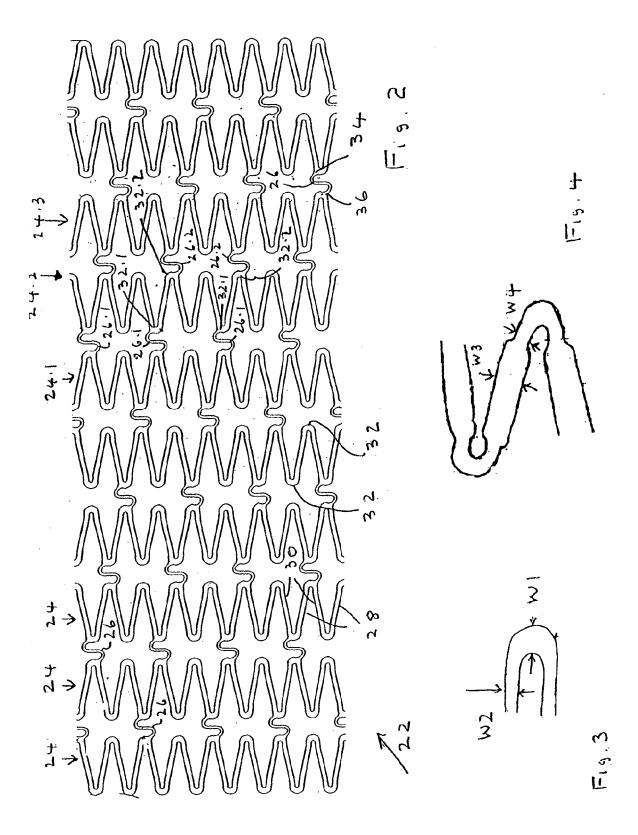
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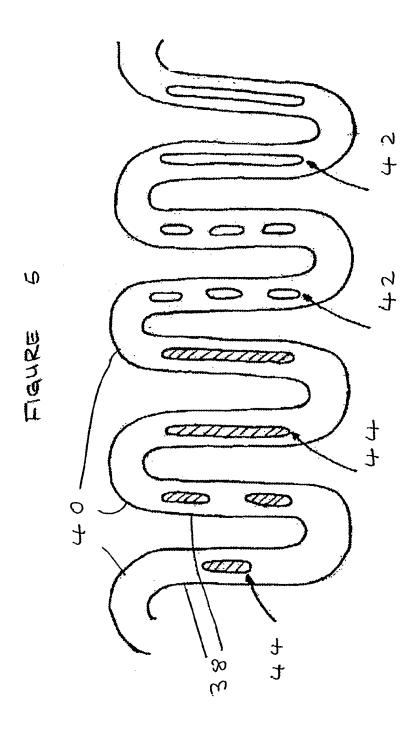
which connect the first ring to a further ring and midway between two additional longitudinals which connect the second ring to another ring, the further longitudinals being spaced the same circumferential distance from one another as the two additional longitudinals are spaced from one another and which is the same distance as the spacing between the longitudinals connecting the first and second rings.

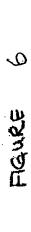
A stent of cylindrical form which comprises a plurality of rings extending 6. around the stent's longitudinal axis, the rings being spaced apart along the axis and being joined to one another by longitudinals each of which spans between one ring and an adjacent ring, each ring being of zig-zag form and comprises a plurality of first bars all of which are parallel to one another and a plurality of second bars all of which are parallel to one another and at an angle to the bars of the first set of bars, first bars alternating with second bars and each first bar being joined at each end thereof to the adjacent second bars by way of hairpin bends, the longitudinals joining the bends of one ring to the bends of the adjacent ring, each longitudinal being of sinusoidal or generally sinusoidal form, there being a first junction where one end of the longitudinal is joined to one ring and a second junction where the other end of the longitudinal is joined to an adjacent ring, said first junction being displaced circumferentially around the stent with respect to the second junction, each ring being a mirror image of the adjacent ring whereby each hairpin bend of said one ring is axially aligned with one of the hairpin bends of said adjacent ring.

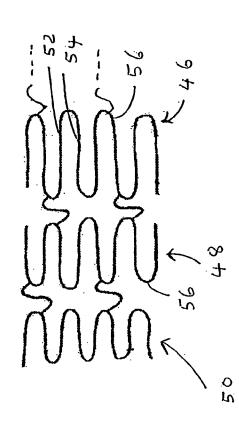
- A stent as claimed in claim 6, wherein each longitudinal is joined to said one ring at the junction between a first bar of said one ring and the hairpin bend at the end of said first bar and is joined to the adjacent ring at the junction between a first bar of said adjacent ring and the hairpin bend at the end of said first bar of the adjacent ring, said first bars being in alignment with one another.
- 8. A stent as claimed in claim 6 or 7, wherein each group of three rings comprises a centre ring, a first adjacent ring on one side of the centre ring and a second adjacent ring on the other side of the centre ring, alternate hairpin bends on one side of the centre ring being joined by longitudinals to the first adjacent ring and alternate hairpin bends on the other side of the centre ring being joined by longitudinals to the second adjacent ring.
- 9. A stent as claimed in any one of claims 1 to 8, wherein each bar of the stent is narrower, considered in the circumferential direction, than the width of the hairpin bends considered in the axial direction.
- 10. A stent as claimed in any one of claims 1 to 9, wherein each bar comprises a centre section and end sections on each side of the centre section, the end sections being narrower, considered in the circumferential direction, than the centre section.











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- (74) Agent: BACON, Brian; Brian Bacon & Associates, 2nd floor, Mariendahl House, Fedsure on Main, Main Road, 7700 Newlands (ZA).
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CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

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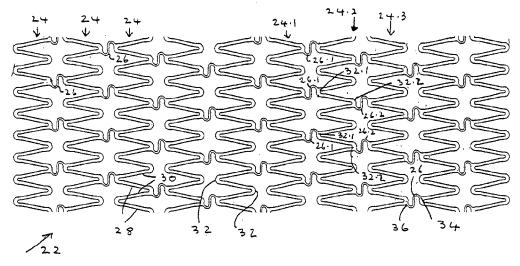
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INTERNATIONAL SEARCH REPORT

Inte nal Application No PCT/ZA 02/00116

A. CLASSI IPC 7	IFICATION OF SUBJECT MATTER A61F2/06								
According to	o International Patent Classification (IPC) or to both national classifica	ation and IPC							
B. FIELDS SEARCHED									
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Documenta	tion searched other than minimum documentation to the extent that s	uch documents are included in the fields so	earched						
Electronic d	lata base consulted during the international search (name of data bas	se and, where practical, search terms used)						
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT								
Category °	Citation of document, with indication, where appropriate, of the rel	Relevant to claim No.							
Х	WO 00 71053 A (NEUSS) 30 November 2000 (2000-11-30) abstract; figures		1-8						
Υ			10						
Y	FR 2 764 794 A (LABORATIORES NYCC 24 December 1998 (1998-12-24) figure 1	10							
X	WO 01 32102 A (ANGIOMED GMBH & COMEDIZINTECHNIK KG) 10 May 2001 (2001-05-10) abstract; figures	1-3							
Further documents are listed in the continuation of box C. Patent family members are listed in annex.									
"A" docume consider the consideration that consideration the considerat	ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another on or other special reason (as specified) nent referring to an oral disclosure, use, exhibition or means ent published prior to the international filling date but han the priority date claimed	 "T" later document published after the international filling date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "3." document member of the same patent family 							
	actual completion of the international search	Date of mailing of the international search report 06/03/2003							
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